

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants:	Michael D. Ries, et al.	)	
		)	
Serial No.:	10/763,314	)	
		)	Group Art
Filed:	January 22, 2004	)	Unit: 3738
		)	
For:	FEMORAL HIP PROSTHESIS AND METHOD OF	)	
	IMPLANTATION	)	
		)	
Examiner:	Bruce E. Snow	)	

**APPELLANTS' REPLY BRIEF UNDER 37 CFR § 41.41**

Mail Stop Appeal Brief  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This is a Reply Brief in response to the Examiner's Answer mailed on December 10, 2007.

Applicant hereby gives permission to the Director of Patents to charge any fees associated with this filing to the Applicants Deposit account # 503352.

**I. Status of Claims**

The present application was filed with 42 claims. Claims 43-57 were added by amendment. Claims 11, 19 and 21-39 have been canceled. Claims 1-10, 12-18, 20 and 40-57 are pending, rejected, and under appeal. Applicant notes that in the Examiner's Answer, the Examiner withdrew the rejections to claims 44, 50, 54 and 57. Claims 1, 40, 41 and 42 are independent claims.

## **II. Grounds of Objection/Rejection to be Reviewed on Appeal**

A. The rejection of claims 1-10, 12-18, 20, 42-57 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

B. The rejection of claims 40-42, 45-57 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,514,288 to Meulink et al.

C. The rejection of claims 40-42, 45-57 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,179,877 to Burke.

D. The rejection of claims 40-42, 45-57 under 35 U.S.C. 102(b) as being anticipated by European Patent 0529036 to Hoffman et al.

### III. Argument

(Please note: the application paragraph numbers referenced in this section refer to the paragraph numbers in the application as filed. In the published application, the paragraph numbers are off by two: if a reader is viewing the published application, the reader must add two to each paragraph number to reference the correct paragraph.)

#### A. Rejection under 35 U.S.C. 112, first paragraph

##### Claims 1-10, 12-18, 20

Claim 1, specifically the phrase “shaped to flex such that, during a normal gait cycle ...” does find support in the original disclosure. In addition to the arguments presented in the Appeal Brief, Appellant would like to point out that the discussions including “during clinical use” in paragraph 37 and “patient gait” in paragraph 46 include no modifiers suggesting that the clinical use and patient gait are considered to be anything but average, or normal. Absent modifiers suggesting extraordinary conditions such as, for example “clinical use under stressed conditions” or “compromised patient gait”, it is clear that normal, non-extraordinary conditions are being discussed. A person of ordinary skill in the art would be familiar with clinical procedures and would easily recognize and understand the meaning of these terms as used in Applicants’ specification.

Regarding the Examiner’s allegation that there is no description or support for the term “significant” in the context of “significant compressive load”, Applicant would like to refer to paragraph 51: “As the femoral head 700 is loaded by the hip joint, a substantial component of the axial compressive force is transmitted to the cancellous 3 and cortical 4 bone in the calcar region 11 from the flange portion 200.” The use of the word

“substantial” certainly provides support for the term “significant”. This description, taken together with the paragraph 37 presentation of the piezoelectric effect known as Wolf’s Law, provides a level of disclosure which would make it clear to one of ordinary skill in the art that the Applicant was indeed in possession of the invention as claimed as of the filing date.

#### Claim 42

Appellants maintain that, as argued in the Appeal Brief, claim 42 finds support in the original text of claim 42.

#### Claim 43

As argued in the Appeal Brief, claim 43 is not new matter, as it is supported by the text of original claim 21. Furthermore, the limitation “...a minimum displacement between the bottom surface of the flange and the proximal section, measured normal to the bottom surface, is less than a maximum cross sectional width of the elongated stem portion, measured perpendicular to the longitudinal axis” can clearly be seen in Figure 4. Distance 310, seen in Figure 4, is defined in Paragraph 35 as “...the linear distance measured between a plane tangent to the bottom surface 220 of the flange portion 200 and a plane through the most distal part of the transitional body portion 300.” The “minimum displacement” is equivalent to distance 310.

Furthermore, the transitional body region 300 is adjacent to the elongated stem portion 400 on its distal side (also paragraph 35). The elongated stem portion includes a tapered portion 450, and in paragraph 42, “The cross sectional area of the tapered portion 450 decreases linearly along the longitudinal length of the tapered portion 450 as the tapered portion 450 transitions down the length of the elongated stem portion 400 from

proximal to distal.” Therefore, the maximum cross sectional width of the elongated stem portion is at its proximal end where it meets the transitional body portion, as seen in Figure 4, and distance 310 is clearly less than that maximum cross sectional width.

#### Claim 45

Claim 45 is not new matter, as alleged by the Examiner. In addition to the arguments presented in the Appeal Brief, Appellants note that the limitation “each cross sectional shape along substantially the entire length of the elongated stem portion is substantially radially symmetrical” finds further support in paragraph 40. To reiterate from paragraph 40, “...the basic substantial shape of the external periphery of the cross-section of the elongated stem portion 400 remains uniform and circular.” A cross-sectional shape that is circular is inherently radially symmetrical; hence if the basic substantial shape remains uniform and is circular, it may be claimed as “substantially radially symmetrical” along “substantially the entire length”.

#### Claim 46

Appellants maintain that, as argued in the Appeal Brief, the claim limitation of a “triangle shape” is clearly supported in Paragraph 40 and Figure 4c.

#### Claim 47

Appellants maintain that, as argued in the Appeal Brief, the claim limitation of “a distal section with a non-circular cross-sectional shape” is clearly taught in Figure 5.

#### Claim 48

Appellants maintain that claim 48 does not constitute new matter. In addition to the arguments presented in the Appeal Brief, claim 48 finds further support in Paragraph

40: “The embodiment of the elongated stem portion 400 shown in FIG. 4 is substantially cylindrical in shape...”

Claim 49

Claim 49 is not new matter, for the same arguments set forth for claim 42 above.

Claim 51

Claim 51 is not new matter, for the same arguments set forth for claim 48 above.

Claim 52

Claim 52 is not new matter, for the same arguments set forth for claim 47 above.

Claim 53

Claim 53 is not new matter, for the same arguments set forth for claim 42 above.

Claim 55

Claim 55 is not new matter, for the same arguments set forth for claim 42 above.

Claim 56

Claim 56 is not new matter, for the same arguments set forth for claim 47 above.

B. Rejection under 35 U.S.C. 102(e) over Meulink et al.

Claims 40, 45 and 50

In addition to the arguments presented in the Appeal Brief, Appellants wish to point out further support found in Meulink that Meulink does not disclose an elongated stem portion “wherein, distally of a medial tip of the flange, each cross-sectional shape along substantially an entire length of the elongated stem portion is substantially radially symmetrical”. In column 3, lines 60-64, referring to Figures 1, 2 and 8, Meulink states “Medial curve tangency 34 comprises the portion of medial curve 32 tangent to

cylindrical femoral shaft 36. In other words, medial curve tangency 34 is located at the point where medial cure 32 ends and cylindrical femoral shaft 36 begins.” Looking at Figures 1, 2, and 8, medial curve tangency 34 is located very nearly halfway along the length of the stem 20, distally of the medial tip of the flange. Nowhere near “substantially the entire length” of the elongated stem portion is “substantially radially symmetrical”.

#### Claims 41, 51, and 54

In regard to claims 41, 51, and 54, the Examiner’s Answer states “It is the Examiner’s position that any shape can be circumscribed by a substantially cylindrical shape”. In this specification, however, the Appellants have set forth the context of the cylindrical shape. It is not any shape, it is the shape defined by the uniform envelope 410 seen in Figure 4 and defined in the specification, paragraphs 38-39: “The elongated stem portion is encompassed within a cylindrically shaped envelope referred to as uniform envelope 410. The cross-sectional shape and the area of the uniform envelope 410 remain(s) substantially uniform through the longitudinal length of the elongated body....The uniform envelope 410 is the same length as the elongated stem portion.” (paragraph 38). The specification clearly sets forth that the cylindrical shape is uniform in cross-section throughout the length of the elongated stem portion. The width of the envelope is defined in paragraphs 38 and 39, and Figure 4: “The uniform envelope 410 has a circular uniform cross-sectional periphery 902 that is defined by the maximum cross-sectional peripheral diameter 905.” and “All the possible features or portions of the elongated stem portion 400...are contained within a maximum diameter 905 of a cross-sectional periphery 902 that defines the cross-section of the uniform envelope 410. Representative shapes of cross-sectional areas viewed from a cross-sectional view cut



plane 900 are shown in Fig. 4a through Fig. 4e.” Looking at the location of view cut 900 in Figure 4 and the cross-section in Figure 4a, it is clear that the cylinder defined in Appellant’s disclosure is of a uniform shape and area that could not accommodate the curved stem disclosed by Meulink, as the wider proximal end of stem would extend out of the cylindrical shape defined by the uniform envelope.

Claims 42, 55, 57

In addition to the arguments presented in the Appeal Brief, Appellants note the Examiner’s admission that any two adjacent cross sectional widths meet the claim limitation. However, the limitation reads “wherein, distally of a medial tip of the flange any two maximum cross sectional widths of the elongated stem portion, measured perpendicular to the longitudinal axis, do not differ by more than ten percent.” Meulink does not disclose a stem in which any two maximum cross sectional widths, not just adjacent ones as suggested by Examiner, do not differ by more than ten percent. In column 4, lines 2-5, Meulink teaches “...the transverse cross-sectional area of the stem in transition section 30 is larger than the transverse cross-sectional area of femoral shaft 36.” This is shown in Figures 2, 3 and 8, in which it is clear that there is a much greater difference than ten percent in the maximum cross-sectional widths of transition section 30 and femoral shaft 36.

Claim 46

Appellants maintain that, as argued in the Appeal Brief, Meulink does not teach an elongated stem portion “wherein each cross sectional shape is selected from the group consisting of a circle, a rectangle a triangle, a hexagon, and a star shape.”

#### Claim 47

Appellants maintain that, in addition to the arguments presented in the Appeal Brief, Meulink does not teach an elongated stem portion comprising a distal section “having a non-circular cross sectional shape” as alleged by the Examiner in the Examiner’s Answer. The stem 20 taught by Meulink comprises a protrusion 40, but the protrusion 40 does not make it non-circular, as is clearly seen in cross-sectional Figures 8 and 9. Furthermore, in column 3, lines 7-10, Meulink teaches: “...femoral stem 20 having porous substance 28 affixed to substrate 26 and protrusion 40 extending from substrate 26. As illustrated in Figs. 2 and 8, protrusion 40 is flush with porous substance 28.” Protrusion 40 is flush and does not make the stem 20 non-circular.

#### Claim 48

Meulink does not anticipate claim 48, for the same reasons argued in the Appeal Brief and set forth above for claim 41.

#### Claim 49

Meulink does not anticipate claim 49, for the same reasons argued in the Appeal Brief and set forth above for claim 42.

#### Claim 52

Meulink does not anticipate claim 52, for the same reasons argued in the Appeal Brief and set forth above for claim 47.

#### Claim 53

Meulink does not anticipate claim 53, for the same reasons argued in the Appeal Brief and set forth above for claim 42.

Claim 56

Meulink does not anticipate claim 56, for the same reasons argued in the Appeal Brief and set forth above for claim 47.

C. Rejection under 35 U.S.C. 102(b) over Burke

Claims 40, 45, 46, 50

The prosthesis disclosed by Burke clearly does not meet the limitation of “wherein, distally of a medial tip of the flange, each cross sectional shape along substantially and entire length of the elongated stem portion is substantially radially symmetrical.” The cross-sectional portion of the stem 14 in Figure 6 does not exhibit radial symmetry, because it cannot be divided into identical sections arrayed around the central axis. Moreover, as seen in Figure 1, no portion of the stem 14 appears to be radially symmetrical in cross section, and clearly the entire length of stem 14 does not exhibit radial symmetry in cross section.

Claims 41, 51, 54

In addition to the arguments presented in the Appeal Brief, see the arguments above under section B, claims 41, 51, 54. A large portion of the curved stem 14 disclosed by Burke would extend out of the cylindrical shape defined by the uniform envelope 410 disclosed in Figures 3, 4 and paragraphs 38 and 39.

Claims 42, 55, 57

In addition to the arguments presented in the Appeal Brief, Appellants note the Examiner’s admission that any two adjacent cross sectional widths meet the claim limitation. However, the limitation reads “wherein, distally of a medial tip of the flange

any two maximum cross sectional widths of the elongated stem portion, measured perpendicular to the longitudinal axis, do not differ by more than ten percent.” Burke does not disclose a stem in which any two maximum cross sectional widths, not just adjacent ones as suggested by Examiner, do not differ by more than ten percent. In Figure 1 it is clear that there is a much greater difference than ten percent in the maximum cross-sectional widths of the proximal and distal ends of stem 14.

#### Claim 47

In addition to the arguments presented in the Appeal Brief, Applicants wish to point out that the cross section of the stem 14 seen in Figures 1 and 2 is clearly rectangular. A rectangle is not a “substantially circular shape” as alleged by the Examiner, and Burke does not disclose a stem with “a proximal section having a substantially circular shape”.

#### Claim 48

Burke does not anticipate claim 48, for the same reasons argued in the Appeal Brief and set forth above for claim 41.

#### Claim 49

Burke does not anticipate claim 49, for the same reasons argued in the Appeal Brief and set forth above for claim 42.

#### Claim 52

Burke does not anticipate claim 52, for the same reasons argued in the Appeal Brief and set forth above for claim 47.

Claim 53

Burke does not anticipate claim 53, for the same reasons argued in the Appeal Brief and set forth above for claim 42.

Claim 56

Burke does not anticipate claim 56, for the same reasons argued in the Appeal Brief and set forth above for claim 47.

D. Rejection under 35 U.S.C. 102(b) over Hoffman et al.

Claims 40, 45, 50

Appellants maintain that, as argued in the Appeal Brief, that Hoffman does not disclose an elongated stem portion in which meets the limitations of the claims. The Examiner presents no evidence that the proximal portion 24 of the stem disclosed by Hoffman is substantially radially symmetrical. And as seen in Figures 2 and 4, the proximal portion 24 does account for a considerable amount of the entire length of the stem 17.

Claims 41, 51 and 54

In addition to the arguments presented in the Appeal Brief, see the arguments above under section B, claims 41, 51, 54. A large portion of the curved stem 17 disclosed by Hoffman would extend out of the cylindrical shape defined by the uniform envelope 410 disclosed in Figures 3, 4 and paragraphs 38 and 39.

Claims 42, 55, 57

In addition to the arguments presented in the Appeal Brief, Appellants note the Examiner's admission that any two adjacent cross sectional widths meet the claim

limitation. However, the limitation reads “wherein, distally of a medial tip of the flange any two maximum cross sectional widths of the elongated stem portion, measured perpendicular to the longitudinal axis, do not differ by more than ten percent.” Burke does not disclose a stem in which any two maximum cross sectional widths, not just adjacent ones as suggested by Examiner, do not differ by more than ten percent. In Figures 2 and 4 it is clear that there is a much greater difference than ten percent in the maximum cross-sectional widths of the proximal 24 and distal 25 ends of stem 17.

#### Claim 46

In addition to the arguments presented in the Appeal Brief, Appellants note that the claim reads “each cross sectional shape is selected from the group consisting of a circle, a rectangle, a triangle, a hexagon, and a star shape.” Clearly the cross sectional shapes of the proximal stem 24 in Figure 2 are not any of the shapes listed in the claim, and the cross section seen in Figure 7 is not any of those shapes. Furthermore, a cross section of distal portion 25, taken near at the indicator line for number 25 in Figure 4, would not be a circle, a rectangle, a triangle, a hexagon, or a star shape.

#### Claim 47

Applicants maintain that, as argued in the Appeal Brief, Hoffman does not disclose a stem portion meeting all the limitation of the claim.

#### Claim 48

Hoffman does not anticipate claim 48, for the same reasons argued in the Appeal Brief and set forth above for claim 41.

Claim 49

Hoffman does not anticipate claim 49, for the same reasons argued in the Appeal Brief and set forth above for claim 42.

Claim 52

Hoffman does not anticipate claim 52, for the same reasons argued in the Appeal Brief and set forth above for claim 47.

Claim 53

Hoffman does not anticipate claim 53, for the same reasons argued in the Appeal Brief and set forth above for claim 42.

Claim 56

Hoffman does not anticipate claim 56, for the same reasons argued in the Appeal Brief and set forth above for claim 47.

**Conclusion**

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellants seek the Board's concurrence at this time.

Dated this 11th day of February, 2008.

Respectfully submitted,

/David Meibos/

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